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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,331	10/04/2000	Pierre Deslongchamps	6670/0H748	6557

7590  
Darby & Darby PC  
805 Third Avenue  
New York, NY 10022

05/15/2002

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary***File Copy*

Application No.

09/679,331

Applicant(s)

DESLONGCHAMPS ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

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### DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is 703-308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Supervisory Patent Examiner, at (703) 308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, drawn to product described as a "macrocyclic compound" comprising general formula (I) classified, for example, in class 530, subclass 317.
  - II. Claims 11 (in part), 12, 13 (in part), 14-17, 18 (in part), 19-23 drawn to a method for preparing a compound of formula (I) using "solution-phase" synthesis. The invention is classified variously in class 530, subclass 338 or class 528, subclass 328, for example.
  - III. Claims 11 (in part), 12, 13 (in part), 14-17, 18 (in part), 19-23 drawn to a method for preparing a compound of formula (I) using "solid-phase" synthesis. The invention is classified variously in class 530, subclass 334 or in class 528, subclass 328, for example.
2. Groups I and II or I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, more than one materially different process can be used to make the product, for

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example, solution phase (Group II) or solid phase (Group III) synthesis. Reaction of different building blocks could also be employed.

3. Groups II and III are different methods. The methods are different because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group III employs an extra step, cleaving samples from a solid support, which is not required by the method of Group II. As a result, Group III requires a different reagent (a solid support) that is not required by Group II. In addition, since Group II does not utilize a solid support, Group II will produce different results than Group III in situations where a solid support is required. Therefore, Groups II and III have different issues regarding patentability and enablement and represent patentably distinct subject matter.
4. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter, restriction for examination purposes as indicated is proper.
5. This application also contains claims directed to the following patentably distinct species of the claimed inventions as set forth below. For Groups I, II, and III see paragraphs 6, 7-11, and 12-16, respectively.

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6. If applicant elects Group I, applicant is also required to elect a single species corresponding to “formula (I)” of claim 1 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like A, B, C, T, X, Y, L, Z, R, and PG when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. For example, picking a single compound from claim 10 would be an acceptable species election since each of the structures drawn in claim 10 define only one compound and include all of the atoms and bonds that are needed to unambiguously define it.

7. If applicant elects the invention of Group II, applicant is also required to elect a single species corresponding to the “first building block” given by formula H-N(X)-CH(R<sub>1</sub>)-C(=O)-A-B-C-Sp-P in step “a” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

8. Furthermore, if applicant elects the invention of Group II, applicant is also required to elect a single species corresponding to the “tether” given by formula H-Y-L-Z-PG<sub>z</sub> in step “b” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like Y, L,

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Z, and PG<sub>z</sub> when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

9. Furthermore, if applicant elects the invention of Group II, applicant is also required to elect a single species corresponding to the “product” of the coupling reaction between the “first building block” and the “tether” in step “b” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

10. Furthermore, if applicant elects the invention of Group II, applicant is also required to elect a single species corresponding to the “unprotected product” of the coupling reaction between the “first building block” and the “tether” in step “c” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

11. Furthermore, if applicant elects the invention of Group II, applicant is also required to elect a single species corresponding to the “macrocyclization product” of the coupling reaction between the “first building block” and the “tether” in step “d” of claim 11 wherein a specific

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structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

12. If applicant elects the invention of Group III, applicant is also required to elect a single species corresponding to the “first building block” given by formula H-N(X)-CH(R<sub>1</sub>)-C(=O)-A-B-C-Sp-P in step “a” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, the applicant must show enough atoms and bonds of the polymer, P, to adequately characterize said polymer for the purposes of a search.

13. Furthermore, if applicant elects the invention of Group III, applicant is also required to elect a single species corresponding to the “tether” given by formula H-Y-L-Z-PG<sub>z</sub> in step “b” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like Y, L, Z, and PG<sub>z</sub> when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

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14. Furthermore, if applicant elects the invention of Group III, applicant is also required to elect a single species corresponding to the “product” of the coupling reaction between the “first building block” and the “tether” in step “b” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, the applicant must show enough atoms and bonds of the polymer, P, to adequately characterize said polymer for the purposes of a search.

15. Furthermore, if applicant elects the invention of Group III, applicant is also required to elect a single species corresponding to the “unprotected product” of the coupling reaction between the “first building block” and the “tether” in step “c” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, the applicant must show enough atoms and bonds of the polymer, P, to adequately characterize said polymer for the purposes of a search.

16. Furthermore, if applicant elects the invention of Group III, applicant is also required to elect a single species corresponding to the “macrocyclization product” of the coupling reaction

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between the “first building block” and the “tether” in step “d” of claim 11 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound (including protecting groups). Applicant should not use notations like X, R<sub>1</sub>, A, B, C, Sp and P when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected. Furthermore, the applicant must show enough atoms and bonds of the polymer, P, to adequately characterize said polymer for the purposes of a search.

17. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Moreover, the above species can be separately classified. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

19. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

22. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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24. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 4:30 p.m.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.  
5/03/02

  
**DR. JYOTHSNA VENKAT PH.D**  
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